Remarks

Telephone Interview with the Examiner

The applicants and the undersigned greatly appreciate the examiner's time and comments during the interview today. The claims have been amended in response to incorporate those features applicants' believe are most important to their invention.

The invention is a two component drug formulation. The first component is designed to rapidly release drug within the mouth, where it is taken up in an effective amount through the buccal or sublingual surface. Suitable drugs are low molecular weight compounds (typically under 350 daltons, see page 6, lines 13-15) or the specifically listed compounds (pages 9-10) that demonstrate rapid onset when administered intraorally (page 7, lines 20-23) since they are not ingested, but are absorbed directly into the systemic circulation. These drugs may also have a low bioavailability if administered orally due to first-pass metabolism (page 6, lines 15-19). The dosage of the drug is low, in the range of 1 microgram to 50 mg, more typically 10 micrograms to 30 mg (page 6, lines 1-2). The second component is designed to be released orally, where it is swallowed for uptake within the gastrointestinal tract. The first intraoral component is released rapidly, in some cases within 10 minutes of contacting the saliva (page 20, lines 1-2). The release of the second component may be immediate, continuously released, or released after a delay over a period of 0.5 to 12 hours (page 8, lines 1-4). The formulation may be chewable (page 8, line 5). The formulation may contain a signaling system between the first and second component (page 15, lines 5-10). The first and second components may consist of a single layer or multiple layers or a core in a tablet or capsule (page 21). These may be coated with a

film or a compression coating (page 21, lines 22-25). The composition may include an effervescent agent (page 22, lines 15-17; page 23, lines 1-3). The second oral component may include a delayed release coating (page 24, lines 24-26) or a sustained release formulation (page 26, lines 24-26) releasing for 0.5 to 24 hours (page 27, line 1).

Rejections Under 35 U.S.C. § 102 and 103

Claims 1-3, 5, 7, 10, 14, 16-18 and 27 were rejected as anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 5,558,879 to Chen et al. ("Chen"). Claims 1-3, 6, 8-11 and 25-29 were rejected as anticipated under 35 U.S.C. §102(b) by U.S. Patent No. 5,053,032 to Barclay et al. ("Barclay"). Claims 1-3, 5, 7, 10, 12 and 29 were rejected as anticipated under 35 U.S.C. 102(a) by EP 1112737 ("EP"). The Examiner rejected claims 4-5, 7, 12-24, and 32 as obvious under 35 U.S.C. § 103 over Barclay in view of U.S. Pat. No. 4,814,181 to Jordan et al. ("Jordan"). The Examiner further rejected claims 4-5, 7, 12-24, and 32 as obvious over Barclay in view of U.S. Pat. No. 6,004,582 to Faour et al. ("Faour"). Applicants respectfully traverse the rejections if they are applied to the new claims.

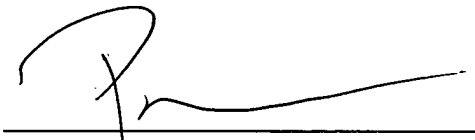
EP 1112737 ("EP") was published on July 4, 2001. An EP is available as prior art only as of its date of publication. The present application was filed on May 15, 2001, more than one month prior to the publication of EP. Therefore, the pharmaceutical composition described in EP is not prior art under 35 U.S.C. 102(a).

None of the prior art discloses or leads one of ordinary skill in the art to a drug formulation which contains (1) a component which is rapidly released in the mouth, has a low molecular weight under 350 daltons, present in a dosage between 10 micrograms and 50 mg, which is absorbed sublingually or buccally, in combination with (2) an inner

second component which is for oral administration. The prior art does not teach the selection of an agent for buccal or sublingual administration as defined by the claims now pending, which is rapidly released and absorbed. Barclay is an osmotic device with slow release. Chen is a controlled release formulation. Neither teaches a two phase system, specific to delivery of drug for an initial rapid intraoral administration, followed by oral administration via the gut. Accordingly, the prior art neither discloses nor makes obvious the claimed subject matter.

Allowance of all claims 33-57 is earnestly solicited.

Respectfully submitted,



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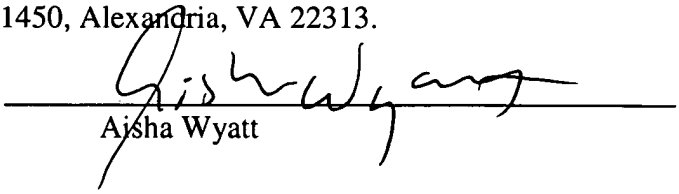

Aisha Wyatt

Date: June 13, 2003